DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
JFK Federal Building, Government Center
Room 2350
Boston, MA 02203

Northeast Division of Survey & Certification

CENTERS FOR MEDICARE & MEDICAID SERVICES

IMPORTANT NOTICE – ACTION NECESSARY

February 5, 2019 Via certified mail

Alexander Finkelstein, M.D.
Laboratory Director
Bridgeport Hospital Laboratory
267 Grant Street
Bridgeport, CT 06610 CLIA number: 07D0099572

RE: **IMPOSITION OF PRINCIPAL SANCTION – IMMEDIATE JEOPARDY--- PROPOSAL OF SANCTIONS CONDITION-LEVEL NON-COMPLIANCE - IMPOSITION NOTICE TO FOLLOW IF PROPOSED SANCTIONS ARE IMPOSED**

Dear Finkelstein:

In order for a laboratory to perform testing under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), Public Law 100-578, it must comply with all CLIA requirements. These requirements are found in section 353 of the Public Health Service Act (42 U.S.C. § 263a) and 42 Code of Federal Regulations, Part 493 (42 C.F.R. § 493). Federal regulations require onsite surveys to determine whether or not a laboratory is in compliance with the applicable regulations. Compliance with these regulations is a condition of certification for the CLIA program.

The Department of Public Health, Connecticut State Agency (SA) conducted a complaint survey of your laboratory that was completed on January 29, 2019. Based on this survey, the Bridgeport Hospital Laboratory was found to be out of compliance with three CLIA conditions.

Specifically, the following conditions were found:

- 42 C.F.R. § 493.1219 - Histopathology;
- 42 C.F.R. § 493.1259 - Laboratory General Supervisor, High Complexity Testing; and
- 42 C.F.R. § 493.1441 - Laboratory Director, High Complexity Testing.

In addition, sixteen standards were also found to be not met.

The serious nature of the deficiencies has resulted in a determination of immediate jeopardy (IJ) to patient health and safety. CMS has reviewed the case and concurs with the SA's findings of IJ.

Notice is hereby given that pursuant to the CLIA and its implementing regulations, CMS is imposing the principal sanction of limitation against your laboratory's CLIA certificate. CMS also proposes to suspend, and subsequently revoke the CLIA Certificate of Accreditation issued to your facility.

IMPOSED SANCTIONS

Pursuant to 42 C.F.R. §§ 493.1812, 493.1840, we are requiring that you take immediate action to remove the IJ. We are imposing, effective February 10, 2019, the principal sanction of limitation for the subspecialty of Pathology: Histopathology.

- 42 C.F.R. § 493.1806, 493.1804(b)(1)(i), 493.1840(d)(2)(i), and 493.1840(a)(3) – Principal Sanction: **Limitation** of the laboratory's CLIA certificate for the subspecialty of Pathology: Histopathology effective February 10, 2019. When a laboratory's CLIA certificate is limited in a specific subspecialty, the laboratory will not be permitted to perform any patient testing in that subspecialty. The laboratory may not test and/or report any patient test results in the subspecialty of Pathology: Histopathology. Additionally, if the certificate is limited, Medicare approval is limited to only those specialties or subspecialties that are authorized by the laboratory's limited certificate. *See* 42 C.F.R. § 493.1808. As a reminder, Medicaid payments will also not be available for Histopathology while the certificate is limited. See 42 C.F.R. §§ 493.440.30(c), 1809.

Before the subspecialty of Pathology: Histopathology can be reinstated, the laboratory must be found competent to perform tests under the subspecialty of Pathology: Histopathology and be in compliance with all applicable CLIA requirements, prior to being certified to perform any testing under the subspecialty of Pathology: Histopathology. The Bridgeport Hospital Laboratory must provide reasonable assurance that the deficient practices that resulted in the current sanction action will not recur before CMS can reinstate the subspecialty of Pathology: Histopathology.

PROPOSED SANCTIONS

Accordingly, pursuant to 42 C.F.R. §§ 493.1806, 493.1812, and 493.1840(a)(3), based on the laboratory's failure to meet all CLIA Conditions, and based on the failure by the owner(s) and director of the laboratory to comply with the certificate requirements and performance standards as evidenced by the deficiencies cited at the January 29, 2019, survey, we are taking action to propose the following sanctions against the Bridgeport Hospital Laboratory's CLIA certificate:

- 42 U.S.C. § 263a(i)(3), 42 C.F.R. §§ 493.1806, 493.1840(a)(3) and 493.1840(e) – Principal Sanction: **Revocation** of the laboratory's CLIA certificate effective April 5, 2019. If imposed, the laboratory has 60 days to appeal the determination to revoke the laboratory's CLIA certificate. If a timely hearing request is received, revocation of the laboratory's CLIA certificate will become effective following the administrative hearing decision, if our determination of non-compliance is upheld.

- 42 C.F.R. §§ 493.1806, 493.1812, 493.1840(a)(3) and 493.1840(d)(2)(i) – Principal Sanction: **Suspension** of the laboratory's CLIA certificate effective February 13, 2019, based on the finding of IJ. If imposed, the suspension will take effect regardless of whether a hearing is

filed and will remain in effect until the laboratory's CLIA certificate is revoked. Under suspension, your laboratory may not legally perform patient laboratory testing. Your laboratory will be allowed to remain in operation, and may perform other procedures (i.e., quality control, personnel recruitment, training, proficiency testing, etc.).

- 42 C.F.R. § 493.1836, Alternative Sanction: **State onsite monitoring,** effective February 13, 2019. CMS will require the state agency to provide intermittent monitoring of the plan of correction to ensure that the laboratory makes the improvements necessary to bring it into compliance. When CMS imposes the sanction of onsite monitoring, the sanction continues until CMS determines that the laboratory has the capability to ensure compliance with all Condition-level requirements.

- 42 C.F.R. §§ 493.1806(c)(3), 493.1810(c)(2)(i), 493.1810(d) and 493.1834 – Alternative Sanction: **Civil Money Penalty (CMP)** in the amount of $10,000 per day for each day of non-compliance effective February 11, 2019. If the laboratory requests a hearing, the CMP amount will not be collected until after the hearing decision is rendered. However, the $10,000/day will begin to accrue on February 11, 2019, and will continue to accrue until it can be verified that the laboratory is in compliance with all Condition-level requirements or the laboratory's CLIA certificate is suspended.

In determining the amount of the penalty, CMS has taken into account the following factors:

(1) The deficiencies cited at the January 29, 2019 survey were so serious as to result in the determination of immediate jeopardy to patient health and safety; (2) the laboratory was found to be out of compliance with three CLIA Conditions and sixteen standards-level CLIA requirements at the survey completed on January 29, 2019; (3) the laboratory failed to provide a qualified General Supervisor and a Laboratory Director to meet minimum requirements in histopathology; (4) the laboratory General Supervisor/Director failed to fulfill his responsibility to ensure that all staff performing pre-analytical, analytical, and post-analytical activities are qualified and have the skills and training necessary to competently perform laboratory test procedures and identify problems that adversely affect test results; (5) the laboratory failed to ensure laboratory staff follow specimen processing procedures to ensure accurate, reliable and timely test results; (6) the laboratory failed to establish and follow policies and procedures to ensure positive identification and optimum integrity of patient specimens from the time of collection through completion of testing and reporting of results; and (7) the laboratory failed to establish and follow policies and effective procedures for an ongoing mechanism to monitor for cross contamination in tissue specimen processing and assure that the appropriate diagnosis is issued on the correct patients.

Reduction of CMP

Pursuant to 42 C.F.R. § 493.1834(e)(2)(iii), if the laboratory waives its right to a hearing,[1] the amount of the CMP may be reduced by 35 percent (35%). If you would like to waive your

[1] *See* 42 C.F.R. § 493.1834(e)(2) for hearing rights regarding proposed CMPs. You will be provided another opportunity to appeal or claim the 35% reduction in a subsequent letter if CMS decides to impose any of the proposed sanctions, including a CMP.

right to a hearing, you must do so by submitting your written notice of waiver to the following address within sixty (60) calendar days from the date of receipt of this notice:

Daniel M. Kristola
Branch Manager
Centers for Medicare & Medicaid Services
Certification and Enforcement Branch
JFK Federal Building, Room-2350
Boston, MA 02203

If a timely request for hearing is filed, i.e., by April 4, 2019, CMS does not collect a CMP until after an ALJ decision upholding the penalty is issued. However, the CMP amount continues to accrue each day beginning with the effective date stated above.

- 42 C.F.R. §§ 493.1806(c)(1), 493.1832, 493.1844(d)(1) and 493.1844(g)(1) – Alternative Sanction: **Directed Portion of a Plan of Correction** effective February 11, 2019. The laboratory will be directed to submit to this office within ten calendar days from the date of the imposition notice a list of the names and addresses of all physicians and other clients who have used some or all of the laboratory's services since September 13, 2018. This list may be used to advise the laboratory's clients of the nature of its non-compliance and the nature and effective date of any sanctions imposed against the laboratory.

- 42 C.F.R. §§ 493.1807(a), 493.1808(a), 493.1842 and 493.1844(d)(3) – Principal Sanction: **Cancellation of the laboratory's approval to receive Medicare payments** for any laboratory services performed on or after February 11, 2019. This sanction will be effectuated even if the laboratory files a timely appeal.

Moreover, in accordance with Section 1902(a)(9)(C) of the Social Security Act and 42 C.F.R. § 440.30(c), payment under the Medicaid program, Title XIX of the Social Security Act, will no longer be available to the laboratory for any laboratory services performed on or after February 11, 2019. ***See*** 42 C.F.R. § 440.2(b).

The laboratory is advised that the above sanctions cannot be avoided by the closure, discontinuation of testing, voluntary withdrawal from the CLIA program, or changes in certificate to a lower level of testing.

Please note that pursuant to 42 C.F.R. § 493.1840(a)(7), failure to comply with an alternative sanction, such as a CMP or a Directed Plan of Correction, is a separate and distinct basis for limitation, suspension, or revocation of any type of CLIA certificate.

When the laboratory's CLIA certificate is suspended, the laboratory will not be permitted to perform any patient testing including waived and provider performed microscopy testing and regardless of whether or not the laboratory charges for the testing.

Also, under revocation, 42 U.S.C. § 263a(i)(3) and 42 C.F.R. § 493.1840(a)(8) prohibit the owner(s) or operator(s) (including director – see 42 C.F.R. § 493.2) from owning or operating (or directing) a

laboratory for at least two years from the date of the revocation. This prohibition applies to the owner(s) as well as the director at the time that the deficiencies were found which led to the current sanction actions.

The laboratory may continue to perform parallel testing on patient specimens if needed to implement corrective actions. However, the laboratory may not report any patient test results during the period when its CLIA certificate is suspended.

If the sanctions become effective as referenced above, in accordance with 42 C.F.R. § 493.1850(a)(2), information regarding the actions against the laboratory's CLIA certificate will appear in the Laboratory Registry for the calendar year in which the actions are imposed. Pursuant to 42 C.F.R. § 493.1844(g)(1), we will notify the general public by posting the information on the Survey & Certification website at https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/SurveyCertificationGenInfo/Termination-Notices.html.

Appeal Rights

If the Bridgeport Hospital Laboratory believes this determination to impose these actions against its CLIA certificate is not correct, the laboratory may request a hearing before an administrative law judge (ALJ) of the Departmental Appeals Board in accordance with 42 C.F.R. § 493.1844(a)(1)-(2) and 42 C.F.R. §§ 498.40 through 498.78. A request for hearing must be filed **electronically** no later than **sixty (60) calendar days** after the date this letter is received (see 42 C.F.R. § 493.1844(f), 493.1844(g), and 493.1834(e)(2)(i)). You should file your request for an appeal (accompanied by a copy of this letter) to the Department Appeals Board Electronic Filing System website (DAB E-file) at https://dab.efile.hhs.gov. Please note: all documents must be submitted in Portable Document Format ("pdf:"). You are **required** to e-file your appeal request unless you do not have access to a computer or internet service. In such circumstances, you may file in writing, but must provide an explanation as to why you cannot file submissions electronically and request a waiver from e-filing in the mailed copy of your request for a hearing. Written request for appeals must also be filed no later than sixty (60) calendar days after the date this letter is received, and must be submitted to the following address:

Department of Health and Human Services
Departmental Appeals Board, MS 6132
Civil Remedies Division
330 Independence Ave, SW
Cohen Building, Room G-644
Washington, D.C. 20201

A copy of the hearing request should be sent to:

Daniel M. Kristola, Branch Chief
Centers for Medicare & Medicaid Services
Certification and Enforcement Branch
JFK Federal Building, Room – 2350
Boston, MA 02203

The request for hearing must contain a statement as to the specific issues and findings of fact and conclusions of law in this determination with which the laboratory disagrees and the basis for the laboratory's contention that the specific issues and/or findings and conclusions are incorrect. Evidence and arguments may also be presented at the hearing, where counsel may represent the laboratory at its own expense. **If a hearing is conducted and CMS' determination is upheld, the laboratory will be assessed a fee to cover the government's cost related to the hearing.** ***See*** 42 C.F.R. § 493.643(d)(2).

As noted above, if a timely request for hearing is filed, i.e., by April 5, 2019, CMS does not collect the CMP or revoke any type of CLIA certificate until after an ALJ hearing that upholds CMS' sanction determination. However, limitation and suspension of the laboratory's CLIA certificate will go into force effective February 10 and February 13, 2019, respectively, and the Directed Portion of a Plan of Correction and cancellation of all Medicare and Medicaid payment are effective February 11, 2019, regardless of whether a hearing is requested. *See* 42 C.F.R. §§ 493.1844(d)(1)-(3) and 493.1844(h)(1).

Please be advised that the determination that a laboratory's deficiencies pose IJ is not subject to appeal. 42 C.F.R. § 493.1844(c)(6) Please also be advised that the determination as to which alternative sanction or sanctions to impose, including the amount of a Civil Money Penalty to impose per day or per violation, is not subject to appeal. *See* 42 C.F.R. § 493.1844(c)(4) and (c)(7).

Please note that in accordance with 42 U.S.C. § 263a(i)(2), CMS is authorized to suspend or limit the CLIA certificate of a laboratory before holding a hearing where the failure to comply with CLIA requirements presents an imminent and serious risk to human health, as has been determined in the case of the Bridgeport Hospital Laboratory. As further provided under this section of the statute, if the laboratory requests a hearing, it is entitled to have the hearing commence within 60 days of the effective date of the suspension or limitation. The laboratory must specify in any request for a hearing to challenge the suspension of its CLIA certificate whether it wishes the hearing to commence within 60 days.

You have ten days from the date of this notice, or until February 15, 2019, to submit in writing any evidence and/or information as to why the proposed sanctions detailed above should not be imposed.

Your laboratory's response should be sent to:

Daniel M. Kristola
Branch Chief
Centers for Medicare & Medicaid Services
Certification and Enforcement Branch
JFK Federal Building, Room – 2350
Boston, MA 02203
Daniel.kristola@cms.hhs.gov

A copy of any response the laboratory makes should also be sent to the SA at the following address:

Barbara S. Cass, R.N.
CLIA Branch Chief
Healthcare Quality and Safety Branch
State of Connecticut, Department of Public Health
410 Capitol Avenue
Hartford, CT 06134

If you have any questions, please contact Dina Caloggero (dina.caloggero@cms.hhs.gov) at 617-565-1286 or Bethzaida Rodriguez (Bethzaida.Rodriguez@cms.hhs.gov) at (617) 565-2146.

Sincerely,

Daniel M. Kristola
Branch Manager
Certification and Enforcement Branch

Enclosure: CMS-2567

Cc: Barbara Cass, Connecticut State Agency
Karen Dyer, CMS, Central Office, Baltimore, M.D.
Amy Daniels, CAP

Dr. Finkelstein - Via certified mail, return receipt # **9171999991703207388734**

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	07D0099572	A. BUILDING _____ B. WING _____	C 01/29/2019

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
BRIDGEPORT HOSPITAL LABORATORY	267 GRANT BRIDGEPORT, CT 06610

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D5028 610H	HISTOPATHOLOGY CFR(s): 493.1219 If the laboratory provides services in the subspecialty of Histopathology, the laboratory must meet the requirements specified in §§493.1230 through 493.1256, §493.1273, and §§493.1281 through 493.1299. This CONDITION is not met as evidenced by: Based on surveyor observation, record review and staff interview, the histopathology laboratory failed to meet the requirements specified in §§493.1230 through 493.1256, §493.1273, and §§493.1281 through 493.1299. The cumulative effect of these systemic problems resulted in the laboratory's inability to ensure the accuracy and reliability of patient test results. Refer to D5311, D5391, D5403, and D5429.	D5028		
D5311 610H	SPECIMEN SUBMISSION, HANDLING, AND REFERRAL CFR(s): 493.1242(a) The laboratory must establish and follow written policies and procedures for each of the following, if applicable: (1) Patient preparation. (2) Specimen collection. (3) Specimen labeling, including patient name or unique patient identifier and, when appropriate, specimen source. (4) Specimen storage and preservation. (5) Conditions for specimen transportation. (6) Specimen processing. (7) Specimen acceptability and rejection. (8) Specimen referral. This STANDARD is not met as evidenced by: Based on record review and staff interview, the	D5311		

LABORATORY DIRECTOR'S OR PROVIDER/SUPPLIER REPRESENTATIVE'S SIGNATURE | TITLE | (X6) DATE

Any deficiency statement ending with an asterisk (*) denotes a deficiency which the institution may be excused from correcting providing it is determined that other safeguards provide sufficient protection to the patients. (See instructions.) Except for nursing homes, the findings stated above are disclosable 90 days following the date of survey whether or not a plan of correction is provided. For nursing homes, the above findings and plans of correction are disclosable 14 days following the date these documents are made available to the facility. If deficiencies are cited, an approved plan of correction is requisite to continued program participation.

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D5311	Continued From page 1	D5311		

laboratory failed to establish written policies and procedures for the use of tampers for tissue specimen processing in the subspecialty of histopathology.

Findings include:

1. Staff interview with the laboratory director (LD) on 1/22/19 at 9:56 AM revealed,
a) 2 of 2 patients had their tissue blocks cross contaminated during the tissue embedding process on 12/4/18. LD stated during the specimen embedding process, the histotechnologist incorrectly utilized the tamper embedding tool which resulted in the cross contamination of paraffin embedded blocks. This resulted in an incorrect diagnosis of histopathology slides for Patient #1 (P1).
b) P1 had 2 samples: one endocervical currettings and one endometrial currettings. Both samples were positive with high grade serous carcinoma and follow-up immunohistochemical (IHC) staining revealed tumor was present in all levels. LD consulted with the GYN Pathology Director at Yale University who agreed with the diagnosis. P1 ordering physician was notified of the diagnosis on 12/6/18.
c) The error was discovered when Patient #1 had a hysterectomy on 12/28/18 at Yale New Haven Hospital. When the tissue from the hysterectomy was examined, no tumor was identified. Yale reexamined the Bridgeport Hospital original histopathology slides and determined the tumor was present therefore it was either entirely removed when the original specimens were collected or the specimens were mixed up or contaminated.
d) Bridgeport hospital ran a proximity report from the CoPath laboratory information system for

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D5311	Continued From page 2	D5311		

specimens embedded at the same time on 12/4/18. Another case, Patient #2 (P2), was identified with serous carcinoma. One case separated the carcinomas. P2 case was embedded first.
e) The middle case between P1 and P2 was a bladder biopsy (Patient #3) (P3). P3 slide was reexamined and it was determined a small piece of serous CA was present on the periphery of the slide and had no bearing on the final diagnosis for P3.
f) Genotyping done on P1's original specimens determined the serous CA was not that of P1 but that of P2. P2's follow-up hysterectomy yielded a diagnosis of serous CA.
g) When it was determined specimens were contaminated, Bridgeport Hospital processing was stopped on 1/11/19.
h) Root Cause Analysis was begun on 1/16/19 and it was determined the tamper used at embedding is the most likely cause of the cross contamination.

2. Record review of the 'Policy for Maintaining Specimen Identity' procedure on 1/28/19 revealed the policy did not address the use of tissue tampers.

3. Record review of the 'Embedding - Routine Embedding' procedure on 1/22/19 revealed the procedure for proper use and cleaning of tissue tampers between specimens was not addressed.

4. Staff interview with histotechnologist #1 (HT1) on 1/24/19 at 1:30 PM revealed:
a) HT1 stated he/she embedded the specimens that were cross contaminated.
b) HT1 stated tampers are kept on the heating block/plate. If a tamper is used, it is placed on top

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D5311	Continued From page 3 of the specimen in the paraffin mold, then removed and placed back on the heating plate to melt the paraffin away and the bottom is wiped with a Kimwipe between specimens. Sometimes an embedder may need to press down to get the specimen on the same plane when using a tamper. c) HT1 stated what may have happened that day was possibly some of the prior patient's specimen when pressing down went up the side of the tamper and only the specimen on the bottom came off when wiping. Residual specimen was then carried over to the next two patients. 5. The laboratory processes 49,491 histopathology specimens annually.	D5311		
D5391 610H	PREANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1249(a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the preanalytic systems specified at §§493.1241 through 493.1242. This STANDARD is not met as evidenced by: Based on record review and staff interview, the laboratory failed to establish and follow policies and procedures for an ongoing mechanism to monitor for cross contamination in tissue specimen processing and assure that the appropriate diagnosis is issued on the appropriate patient in the subspecialty of histopathology. Findings include:	D5391		

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D5391	Continued From page 4	D5391		

1. Staff interview with the laboratory director (LD) on 1/22/19 at 9:56 AM revealed, 2 of 2 patients had their tissue blocks cross contaminated during the tissue embedding process on 12/4/18. LD stated during the specimen embedding process, the histotechnologist incorrectly utilized the tamper embedding tool which resulted in the cross contamination of the paraffin embedded blocks. This resulted in an incorrect diagnosis of high grade serous carcinoma.

2. Record review of the 'Policy for Maintaining Specimen Identity' procedure on 1/28/19 revealed the policy did not address the use of tissue tampers.

3. Record review of the 'Embedding - Routine Embedding' procedure on 1/22/19 revealed the procedure for proper use and cleaning of tissue tampers between specimens was not addressed.

4. Record review on 1/23/19 of the Pathology Department Quality Assurance (QA) Log for floater issues revealed: a) Four cases were reported between 6/17/16 and 8/18/17.
b) Floaters were not documented from 8/19/17 to 1/23/19.

5. Staff interview with the histology section superviosr #1 on 1/22/19 at 10:23 AM stated pathologists do not routinely report in a QA back to histology staff when they see floaters.

6. Staff interview with the histopathology technical supervisor on 1/23/19 at 10:30 AM stated the process used at Bridgeport Hospital for floaters is to send the histology general supervisor an email with the information for

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D5391	Continued From page 5 investigation and documentation. 7. The laboratory processes 49,491 histopathology specimens annually.	D5391		
D5403 400M 610H	PROCEDURE MANUAL CFR(s): 493.1251(b) The procedure manual must include the following when applicable to the test procedure: (1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in §493.1242. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in §493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (13) The laboratory's system for entering results	D5403		

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in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values.
(14) Description of the course of action to take if a test system becomes inoperable.

This STANDARD is not met as evidenced by:
A. Based on record review and staff interview, the laboratory failed to establish and follow written step by step procedures to ensure positive identification and correct specimen embedding of tissue specimens while utilizing the tamper embedding tools in the subspecialty of histopathology.

Findings include:

1. Record review of the 'Embedding - Routine Embedding' procedure on 1/22/19 revealed the following:
a) Procedure Step #8: "Using warmed forceps, apply gentle but equal pressure to the specimen so that it is flush against surface of mold, while moving the mold to a cooling area. There are tissue tamps that are available which have a larger surface area to exert an equal distribution of force ... Forceps and/or tampers should be wiped periodically during the embedding process to avoid carry-over from sample to sample."
b) Step by step procedure for proper use of 'tissue tamps' was not included.
c) Step by step procedure for cleaning of forceps and/or tampers was not included.

2. Staff interview with histotechnologist #1 (HT1) on 1/24/19 at 1:30 PM revealed:
a) HT1 stated he/she embedded the specimens that were cross contaminated.

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b) HT1 stated tampers are kept on the heating block/plate. If a tamper is used, it is placed on top of the specimen in the paraffin mold, then removed and placed back on the heating plate to melt the paraffin away and the bottom is wiped with a Kim-wipe between specimens. Sometimes an embedder may need to press down to get the specimen on the same plane when using a tamper.
c) HT1 stated what may have happened that day was possibly some of the prior patient's specimen when pressing down went up the side of the tamper and only the specimen on the bottom came off when wiping. Residual specimen then carried over to the next two patients.

B. Based on surveyor observation, record review and staff interview, the laboratory failed to follow written policies and procedure to ensure correct specimen processing of tissue specimens in the subspecialty of histopathology.

Findings include:

1. Surveyor observation of the histology laboratory area on 1/28/19 at 3:20 PM revealed three tissue processors in the laboratory: Leica VIP 300 #1 serial number (SN) 0653/03.2003, Leica VIP 300 #2 SN1185/05.2005 and Leica ASP6025 #3 SN 0820/2016.06.

2. Record review of the 'Routine Preparation of Tissue for Processing and Schedule of Tissue Programs" procedure as compared to programmed cycles for the above processors on 1/28/19 revealed the following:
a) Short cycle processing schedule (2)(2):

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Step	Procedure (minutes)	VIP #1 & #2
Absolute Alcohol	15	60
Absolute Alcohol	30	60
Xylene	15	30
Xylene	30	60
Wax	15	60
Wax	30	30
Wax	30	60

b) Fatty tissue processing schedule for 3 wax steps: procedure states 60 degrees Celsius (C) and processor #3 indicates 65 C.
c) Routine processing schedule

Step	Procedure (minutes)	ASP6025 #3
Formalin	30	120
Processing H2O	Not listed	1
Formalin	90	Not listed
70% Alcohol	30	30
80% Alcohol	60	60
95% Alcohol	60	120
95% Alcohol	60	Not listed
Absolute Alcohol	60	30
Absolute Alcohol	60	30
Absolute Alcohol	Not listed	60
Xylene	60	45
Xylene	60	45
Xylene	Not listed	45
Wax	30 @ 60 C	30 @ 65 C
Wax (2 steps)	60 @ 60 C	30 @ 65 C

3. Staff interview with the histology section supervisor on 1/28/19 at 3:30 PM confirmed the above findings.

4. The laboratory processes 49,491 histopathology specimens annually.

C. Based on record review and staff interview the

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laboratory failed to establish a step-by-step procedure for coagulation reagent rollover studies in the specialty of hematology.

Findings include:

1. Record review on 1/24/19 of the hematology policy and procedure for 'New reagent lot number correlation with old lot number and validation of reference range' signed by the laboratory director on 1/22/19 with an effective date of 1/2019 revealed the following step by step procedures were not addressed:
a) The validation and verification of international sensitivity index (ISI) value when a new lot of thromboplastin reagent is placed into use for the calculation of international normalized ratio (INR).
b) The manual verification of INR calculation.
c) How to change the ISI value in the coagulation analyzer.
d) The calculation of the normal patient Prothrombin Time (PT) mean study.

2. Record review on 1/24/19 of the hematology policy and procedure for 'Protocol for Evalutating New Reagent Lots' effective 12/2017 revealed the following step by step procedures were not addressed:
a) The validation and verification of international sensitivity index (ISI) value when a new lot of thromboplastin reagent is placed into use for the calculation of international normalized ratio (INR).
b) The manual verification of INR calculation.
c) How to change the ISI value in the coagulation analyzer.
d) The calculation of the normal patient Prothrombin Time (PT) mean study.
e) Running patient correlation studies.
f) Validating the reference range.

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3. Staff interview with hematology testing personnel #1 (HTP1) on 1/24/19 at 2:00 PM confirmed the above findings. HTP1 stated the laboratory is in the process of revising and combining its procedures for coagulation reagent rollover studies.

4. The laboratory performs 40,947 coagulation tests annually.

D5411 TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT — D5411

110H CFR(s): 493.1252(a)

Test systems must be selected by the laboratory. The testing must be performed following the manufacturer's instructions and in a manner that provides test results within the laboratory's stated performance specifications for each test system as determined under §493.1253.

This STANDARD is not met as evidenced by:
Based on record review and staff interview, the laboratory failed to follow the manufacturer's instructions for patients with equivocal test results in the subspecialty of bacteriology.

Findings include:

1. Record review on 1/22/19 of the Panther instrument printout for Gonorrhea(GC)/Chlamydia (CT) testing performed on 1/8/19 revealed:
a) Patient #4 (P4) had an equivocal result for GC.
b) Hand written next to the equivocal results was the statement, "Repeat (1st also GC equiv)."

2. Record review on 1/22/19 of the final test report for P4 revealed, Equivocal was listed in the

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D5411	Continued From page 11 value column for Neisseria gonorrhoeae (GC), DNA Probe. 3. Record review on 1/22/19 of the laboratory's 'Panther System for GC & Chlamydia' procedure revealed: a) Test Interpretation - QC/patient Result, "Initial equivocal and invalid test results should be retested." b) The reporting parameters for patients who have equivocal results that are verified upon repeat testing are not listed. 4. Record review on 1/22/19 of the 'Hologic Aptima Combo 2 Assay (Panther System)' manufacturer's instructions Rev. 005, revealed: a) Test Interpretation - QC/patient Result, i. Section A. Test Interpretation: "Initial equivocal and invalid test results should be retested. ii. Section D. Patient Test Results, #2a Initial results: "GC Equiv - Sample should be retested. iii. Section D Patient Test Results, #2b Retest results: "GC Equiv - Indeterminate, a new specimen should be collected." 5. Staff interview with the microbiology general supervisor on 1/22/19 at 2:00 PM confirmed the above findings. 6. The laboratory performs 5,579 GC PCR tests on the Panther instrument annually.	D5411		
D5429 400B 610H	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1) For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at least the	D5429		

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frequency specified by the manufacturer.
This STANDARD is not met as evidenced by:
A. Based on record review and staff interview the laboratory failed to perform and document preventative maintenance for laboratory equipment in the subspecialty of histopathology.

Findings include:

1. Record review on 1/28/19 of the 2017 and 2018 Dako Autostainer Link 48 Instrument System, Serial Number AS48-0264-01 maintenance records revealed 2018 preventative maintenance documentation was not available.

2. Record review of the Dako Autostainer User guide on 1/28/19 revealed "Annual maintenance is essential for reliable operation of the Dako Autostainer. Without preventative maintenance, the reliability and the life of the Dako Autostainer may be compromised."

3. Staff interview with histology section supervisor #1 (HSS1) on 1/28/19 at 11:50 AM confirmed preventative maintenance was not done in 2018. HSS1 further stated the laboratory is looking for a vendor to service the Autostainer because due to the age of the instrument, the manufacturer will no longer service.

4. The laboratory processes 49,491 histopathology specimens annually.

B. Based on record review and staff interview the laboratory failed to document routine maintenance and function checks for laboratory equipment in the specialty of hematology.

Findings include:

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1. Record review of the Sysmex Slide Maker, Serial Number (SN#) 11745 maintenance logs on 1/24/19 revealed the laboratory failed to document the required maintenance and function checks as listed below.
a) February 2018: Two weeks of weekly maintenance.
b) March 2018: No weekly maintenance.
c) June 2018: No weekly maintenance.
d) September 2018: No weekly maintenance.
e) October 2018: Three weeks of weekly maintenance.
f) December 2018: No weekly maintenance.

2. Record review of the Siemens BCS-XP coagulation analyzers, SN# 152114 and SN# 152115 maintenance logs on 1/24/19 revealed:
a) One weekly maintenenace documentation was missing in January and April 2018 for both coagulation analyzers.
b) One weekly maintenance documentation was missing in November 2018 for analyzer with SN# 152115.
c) Semiannual maintenance was not performed or documented in 2018 for both analyzers.

3. Review of the manufacturer's operator manual for the above equipments on 1/24/19 revealed maintenance protocols need to be performed on a daily, weekly, monthly and semiannual schedule in order to ensure accurate and reliable test results.

4. Staff interview with hematology testing personnel #1 on 1/24/19 at 11:00 AM confirmed the laboratory failed to document weekly and semiannual maintenance and function checks for the above equipments as required by the

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D5429	Continued From page 14 manufacturer. 5. The laboratory performs 12,276 manual differentials and 40,947 coagulation tests annually in the specialty of hematology.	D5429		
D5441 400M	CONTROL PROCEDURES CFR(s): 493.1256(a)(b)(c)(g) (a) For each test system, the laboratory is responsible for having control procedures that monitor the accuracy and precision of the complete analytic process. (b) The laboratory must establish the number, type, and frequency of testing control materials using, if applicable, the performance specifications verified or established by the laboratory as specified in §493.1253(b)(3). (c) The control procedures must-- (c)(1) Detect immediate errors that occur due to test system failure, adverse environmental conditions, and operator performance. (c)(2) Monitor over time the accuracy and precision of test performance that may be influenced by changes in test system performance and environmental conditions, and variance in operator performance. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on record review and staff interview, the laboratory failed to document quality control (QC) procedures for the TS refractometer. Findings include: 1. Record review on 1/24/19 of the laboratory's	D5441		

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D5441	Continued From page 15 urinalysis and body fluid QC records revealed, the laboratory failed to document QC for the Goldberg TS refractometer SN# 01751-0306. 2. Record review of the laboratory's procedure for 'Specific Gravity TS meter' on 1/24/19 revealed two levels of QC must be performed using "Liquicheck 1 and 2" on each day of testing patient samples. 3. Staff interview with hematology testing personnel #1 on 1/24/19 at 2:00 PM confirmed the above findings and stated QC is not performed. 4. The laboratory performs approximately 216 manual specific gravity tests annually.	D5441		
D5789 310M	TEST RECORDS CFR(s): 493.1283(b) Records of patient testing including, if applicable, instrument printouts, must be retained. This STANDARD is not met as evidenced by: Based on record review and staff interview the laboratory failed to record and retain the original patient results for the AmniSure test method in the specialty of chemistry. Findings include: 1. Record review of the AmniSure intermediate worksheets on 1/24/19 revealed patient results were not recorded or retained in 2017 and 2018. 2. Record review of the testing personnel training and competency checklist on 1/24/19 revealed "document internal control and patient result on the AmniSure ROM log sheet."	D5789		

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3. Staff interview with the chemistry general supervisor on 1/24/19 at 12:45 PM confirmed patient test results were transcribed directly into the laboratory information system and not recorded or retained on intermediate worksheets.

4. Approximately 126 AmniSure tests are performed annually.

D6076 LABORATORY DIRECTOR D6076
CFR(s): 493.1441

The laboratory must have a director who meets the qualification requirements of §493.1443 of this subpart and provides overall management and direction in accordance with §493.1445 of this subpart.

This CONDITION is not met as evidenced by:
Based on surveyor observation, record review and staff interview, the laboratory director failed to provide overall management and direction in accordance with §493.1445. The cumulative effect of this lack of oversight resulted in the laboratory director's inability to ensure the accuracy and reliability of patient test results in the subspecialty of histopathology.

Findings include:

1. The laboratory director failed to ensure testing systems developed and used by the laboratory provide quality services for all aspects of test performance. Refer to D6082.

2. The laboratory director failed to ensure personnel follow the procedure manual as written. Refer to D6087.

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D6076	Continued From page 17 3. The laboratory director failed to ensure that the quality assessment programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur. Refer to D6094. 4. The laboratory director failed to ensure: a) Prior to testing patient specimens, all personnel receive the appropriate training and have demonstrated that they can perform all testing operations reliably. b) Identify training needs, needs for remedial training or continuing education to improve skills. c) All personnel maintained competency for tissue specimen processing. Refer to D6102 and D6103.	D6076		
D6082	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(1) The laboratory director must ensure that testing systems developed and used for each of the tests performed in the laboratory provide quality laboratory services for all aspects of test performance, which includes the preanalytic, analytic, and postanalytic phases of testing. This STANDARD is not met as evidenced by: Refer to D5311, D5391, D5403 and D5411	D6082		
D6087	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(3)(iii) The laboratory director must ensure that laboratory personnel are performing the test methods as required for accurate and reliable results. This STANDARD is not met as evidenced by: Refer to D5311, D5403, and D5411	D6087		
D6094	LABORATORY DIRECTOR RESPONSIBILITIES	D6094		

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D6094	Continued From page 18 CFR(s): 493.1445(e)(5) The laboratory director must ensure that the quality assessment programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur. This STANDARD is not met as evidenced by: Refer to D5391	D6094		
D6102	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(12) The laboratory director must ensure that prior to testing patients' specimens, all personnel have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results. This STANDARD is not met as evidenced by: Refer to D6120	D6102		
D6103	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(13) The laboratory director must ensure that policies and procedures are established for monitoring individuals who conduct preanalytical, analytical, and postanalytical phases of testing to assure that they are competent and maintain their competency to process specimens, perform test procedures and report test results promptly and proficiently, and whenever necessary, identify needs for remedial training or continuing education to improve skills. This STANDARD is not met as evidenced by: Based on record review and staff interview, the laboratory director failed to ensure histology	D6103		

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D6103	Continued From page 19 personnel were competent in the embedding process utilizing the tissue tampers in the subspecialty of histopathology. Findings include: 1. Record review of the histology staff 2017 and 2018 competency records on 1/23/19 revealed competency documentation for 9 of 9 personnel for the use of tissue tampers was not available. 2. Staff interview with histology section supervisor #1 on 1/23/19 at 11:45 AM confirmed the above finding. Also Refer to D6120.	D6103		
D6117	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(4) The technical supervisor is responsible for establishing a quality control program appropriate for the testing performed and establishing the parameters for acceptable levels of analytic performance and ensuring that these levels are maintained throughout the entire testing process from the initial receipt of the specimen, through sample analysis and reporting of test results. This STANDARD is not met as evidenced by: Refer to D5311 and D5403.	D6117		
D6120	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(7)(8) (7) The technical supervisor is responsible for identifying training needs and assuring that each individual performing tests receives regular in-service training and education appropriate for the type and complexity of the laboratory services performed;	D6120		

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(8) Evaluating the competency of all testing personnel and assuring that the staff maintain their competency to perform test procedures and report test results promptly, accurately and proficiently.
This STANDARD is not met as evidenced by:
Based on record review and staff interview, the technical supervisor failed to ensure appropriate training and documentation for all staff involved in the specimen processing of tissue specimens in the subspecialty of histopathology.

Findings include:

1. Staff interview with the laboratory director (LD) on 1/22/19 at 9:56 AM revealed, 2 of 2 patients had their tissue blocks cross contaminated during the tissue embedding process on 12/4/18. LD stated during the specimen embedding process, the histotechnologist incorrectly utilized the tamper embedding tool which resulted in the cross contamination of the paraffin embedded blocks. This resulted in an incorrect diagnosis of high grade serous carcinoma.

2. Record review of histotechnogist #1's (HT1) training records on 1/23/19 revealed to following:
a) HT1 was hired May 12, 2008.
b) Training records for the embedding process were not available.

3. Staff interview with histology section supervisor #1 on 1/23/19 at 10:45 AM confirmed the above findings.

4. Staff interview with HT1 on 1/24/18 at 1:30 PM revealed:
a) Employed since May 2008
b) HT1 training took place during the was first

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few weeks which consisted of reading manuals.
c) HT1 currently performs embedding, sectioning and staining of tissue specimens.
c) HT1 stated embedding training documentation was not available.

5. Record review of histology lab aide #1's (HLA1) employee records on 1/23/19 revealed:
a) Initial documentation of histology job competency verification for tissue embedding was signed by histology section supervisor #2 on 2/24/17.
b) Above verification form for the tissue embedding task states, "Reduces cross contamination of tissue from block to block ("floaters") by using clean molds and keeping work surfaces free of debris and excess paraffin."
c) Tissue tamper training documentation was not available.

6. Staff interview with HLA1 on 1/23/19 at 1:05 PM stated:
a) HLA1 was trained to embed tissue specimens in 2017.
b) HLA1 was embedding in 2017 and throughout 2018.

7. Record review on 1/24/19 of the May 2017 training documentation for 2 of 2 new grossing testing personnel revealed:
a) The initial training form is a 'competency assessment form' for the 6 required elements and was reviewed and signed by the laboratory director.
b) Training documentation of the development of the knowledge and skill to perform macroscopic gross examination of tissue specimens was not available.

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D6120	Continued From page 22 8. Staff interview with the histopathology technical supervisor on 1/24/19 at 11:35 AM revealed: a) A pathologist assistant (PA1) performed the training of the 2 of 2 new grossing testing personnel. b) PA1's training documentation was not available. 9. Staff interview with grossing testing personnel #1 (GTP1) on 1/28/19 at 3:40 PM revealed: a) GTP1 started grossing small biopsy specimens May 2017 and was trained by PA1. b) Training documentation of the above was not available. 10. The laboratory processes 49,491 histopathology specimens annually.	D6120		
D6125	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(8)(v) The procedures for evaluation of the competency of the staff must include, but are not limited to assessment of test performance through testing previously analyzed specimens, internal blind testing samples or external proficiency testing samples. This STANDARD is not met as evidenced by: Based on record review and staff interview, the technical supervisor failed to ensure competency assessment for all testing personnel (TP) includes testing previously analyzed specimens, blind samples or external proficiency testing (PT) samples in the specialty of immunohematology. Findings include: 1. Record review on 1/28/19 of the blood bank	D6125		

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D6125	Continued From page 23 laboratory's 2017 and 2018 'Annual Competency Evaluation Checklist Bridgeport Hospital Blood Bank' and the 2017 and 2018 College of American pathologists (CAP) TP PT rotation chart revealed the laboratory failed to provide evidence or documentation for the following: a) 10 of 10 TP did not examine previously analyzed specimens, blind samples or external PT material in all platforms to accurately assess their skills in 2017. b) 8 of 8 TP did not examine previously analyzed specimens, blind samples or external PT material in all platforms to accurately assess their skills in 2018. 2. Staff interview with the blood bank general supervisor on 1/28/19 at 10:00 AM confirmed the above findings. 3. The laboratory performs 54,430 tests annually in the specialty of immunohematology.	D6125		
D6141	GENERAL SUPERVISOR CFR(s): 493.1459 The laboratory must have one or more general supervisors who are qualified under §493.1461 of this subpart to provide general supervision in accordance with §493.1463 of this subpart. This CONDITION is not met as evidenced by: Based on record review and staff interview, the laboratory failed to have a qualified general supervisor (GS) in all specialties/subspecialties of patient testing. Refer to D6143.	D6141		
D6143	GENERAL SUPERVISOR QUALIFICATIONS CFR(s): 493.1461	D6143		

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(a) The general supervisor must possess a current license issued by the State in which the laboratory is located, if such licensing is required; and
(b) The general supervisor must be qualified as a--
(b)(1) Laboratory director under §493.1443; or
(b)(2) Technical supervisor under §493.1449.
(c) If the requirements of paragraph (b)(1) or paragraph (b)(2) of this section are not met, the individual functioning as the general supervisor must--
(c)(1)(i) Be a doctor of medicine, doctor of osteopathy, or doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the laboratory is located or have earned a doctoral, master's, or bachelor's degree in a chemical, physical, biological or clinical laboratory science, or medical technology from an accredited institution; and
(c)(1)(ii) Have at least 1 year of laboratory training or experience, or both, in high complexity testing; or
(c)(2)(i) Qualify as testing personnel under §493.1489(b)(2); and
(c)(2)(ii) Have at least 2 years of laboratory training or experience, or both, in high complexity testing; or
(c)(3)(i) Except as specified in paragraph (3)(ii) of this section, have previously qualified as a general supervisor under §493.1462 on or before February 28, 1992.
(c)(3)(ii) Exception. An individual who achieved a satisfactory grade in a proficiency examination for technologist given by HHS between March 1, 1986 and December 31, 1987, qualifies as a

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general supervisor if he or she meets the requirements of §493.1462 on or before January 1, 1994.
(c)(4) On or before September 1, 1992, have served as a general supervisor of high complexity testing and as of April 24, 1995--
(c)(4)(i) Meet one of the following requirements:
(c)(4)(i)(A) Have graduated from a medical laboratory or clinical laboratory training program approved or accredited by the Accrediting Bureau of Health Education Schools (ABHES), the Commission on Allied Health Education Accreditation (CAHEA), or other organization approved by HHS.
(c)(4)(i)(B) Be a high school graduate or equivalent and have successfully completed an official U.S. military medical laboratory procedures course of at least 50 weeks duration and have held the military enlisted occupational specialty of Medical Laboratory Specialist (Laboratory Technician).
(c)(4)(ii) Have at least 2 years of clinical laboratory training, or experience, or both, in high complexity testing; or
(c)(5) On or before September 1, 1992, have served as a general supervisor of high complexity testing and--
(c)(5)(i) Be a high school graduate or equivalent; and
(c)(5)(ii) Have had at least 10 years of laboratory training or experience, or both, in high complexity testing, including at least 6 years of supervisory experience between September 1, 1982 and September 1, 1992.
(d) For blood gas analysis, the individual providing general supervision must--
(d)(1) Be qualified under §§493.1461(b)(1) or (2),

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or 493.1461(c); or
(d)(2)(i) Have earned a bachelor's degree in respiratory therapy or cardiovascular technology from an accredited institution; and
(d)(2)(ii) Have at least one year of laboratory training or experience, or both, in blood gas analysis; or
(d)(3)(i) Have earned an associate degree related to pulmonary function from an accredited institution; and
(d)(3)(ii) Have at least two years of training or experience, or both in blood gas analysis.
(e) The general supervisor requirement is met in histopathology, oral pathology, dermatopathology, and ophthalmic pathology because all tests and examinations, must be performed:
(e)(1) In histopathology, by an individual who is qualified as a technical supervisor under §§493.1449(b) or 493.1449(l)(1);
(e)(2) In dermatopathology, by an individual who is qualified as a technical supervisor under §§493.1449(b) or 493.1449(l) or (2);
(e)(3) In ophthalmic pathology, by an individual who is qualified as a technical supervisor under §§493.1449(b) or 493.1449(1)(3); and
(e)(4) In oral pathology, by an individual who is qualified as a technical supervisor under §§493.1449(b) or 493.1449(m).

This STANDARD is not met as evidenced by:
Based on record review and staff interview, the laboratory failed to have a qualified general supervisor (GS) in the subspecialty of histopathology.

Findings include:

1. Record review on 1/29/19 of the laboratory's signed CMS 209 form revealed 23 general

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D6143	Continued From page 27 supervisors listed with no specialties indicated. 2. Record review on 1/29/19 of the laboratory's CMS 116 form signed 1/28/19 revealed the specialty/subspecialty of pathology and histopathology with an annual volume of 49,491 tests. 3. Record review on 1/29/19 of the laboratory's organizational chart 'Department of Pathology & Laboratory Medicine Organizational Chart (CLIA)' revealed two general supervisors for histopathology. 4. Record review on 1/29/19 of 2 of 2 histopathology general supervisor credentials revealed the following educational qualifications: a) Histopathology general supervisor #1 holds a master of science degree. b) Histopathology general supervisor #2 holds a bachelor of science degree. c) The above educational qualifications do not meet the general supervisor requirement in histopathology. 5) Staff phone interview with the laboratory director on 1/29/19 at 4:10 PM confirmed the above findings.	D6143		